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EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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09/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/728,566

Applicant(s)

JAHNG, TAE-AHN

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-42 and 44-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-42 and 44-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 08/21/2007, 6/20/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58 and 61-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 58, 61 and 62 recite the limitation "a monolith" in lines 2-3, line 2, and lines 2-3, respectfully, and this limitation does not appear to be disclosed in the originally filed disclosure and it is therefore new matter. Furthermore, Applicant has not pointed out in his "Remarks" where this limitation is supported in the disclosure.

Claim Objections

Claims 42, 46-57 and 61-62 are objected to because of the following informalities:

In claim 42, lines 3-6, the claim recites "wherein the first and second bone securing assemblies secure the rod at least partially between the exterior of a first vertebra and a second vertebra such that the connection system limits movement of the

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first vertebra relative to the second vertebra." Because positively claiming a part of the human body is not permitted, the examiner is interpreting this language to be functional. It is noted that for clarification purposes, applicant should amend the language to recite --wherein the first and second bone securing assemblies **are adapted to secure the rod at least partially between the exterior of a first vertebra and a second vertebra** such that the connection system limits movement of the first vertebra relative to the second vertebra-- to be clearer for examination purposes. Claim 46, lines 10 and 19-21 and claim 52, lines 10 and 19-20 contain the same or similar language that should also be amended to recite --adapted to secure-- to be clearer for examination purposes.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39, 41-42, 46-48, and 52-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Paul et al. (US 20040236327).

Paul et al. discloses embodiments/interchangeable components of a connection system comprising a first bone coupling assembly (e.g. ref. #220); a rod (FIG. 12-12A)

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comprising a first end (ref. #102, left, FIG. 12-12A) including a surface received at least partially within and coupled to the first bone coupling assembly (as shown in FIG 21); a second end portion (ref. #102, right, FIG. 12-12A), a longitudinal member (ref. #110, FIG. 12-12A) located between the first end and the second end, coupled to the first end, and coupled to the second end; and a spacer (ref. #106) located between the first and second ends and circumferentially disposed about the longitudinal member the longitudinal wherein the first and second ends substantially limit motion of the spacer about the longitudinal member. The longitudinal member comprises a braided metal wire structure comprising a plurality of interwoven metal wires (see FIG. 14). The connection system further comprising a second bone coupling assembly connected to the rod at a different location than the first bone coupling assembly and wherein the first and second bone securing assemblies are adapted to secure the rod at least partially between the exterior of a first vertebra and a second vertebra such that the connection system limits movement of the first vertebra relative to the second vertebra (see FIG. 21).

Claims 39, 42, 46, 51-52, 57 and 59-60 are rejected under 35 U.S.C. 102(e) as being anticipated by McAfee (US 20040143264).

McAfee discloses a connection system for use in a bone fixation device, comprising a first bone coupling assembly (e.g. FIG. 9); a rod comprising a first end, or first element (see FIG. 11, rod sleeve, right), including a surface received at least partially within and coupled to the first bone coupling assembly; a second end, or second element (see FIG. 11, rod sleeve, left), a longitudinal member ("rod") located

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between the first end and the second end, coupled to the first end, and coupled to the second end; and a spacer, or third element (FIG. 11, "bumper") located between the first and second ends and circumferentially disposed about the longitudinal member wherein the first and second ends portions substantially limit motion of the spacer about the longitudinal member. A second bone coupling assembly is connected to the rod at a different location than the first bone coupling assembly and wherein the first and second bone securing assemblies are adapted to secure the rod at least partially between the exterior of a first vertebra and a second vertebra such that the connection system limits movement of the first vertebra relative to the second vertebra. The third element comprises a synthetic spacer (UHMWPE "bumper"). The first and second end each have a cross-sectional area that is greater than a cross-sectional area of the longitudinal member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-45, 49-51 and 55-62 are rejected under 35 U.S.C. 103(a) as being obvious over Paul et al. (US 20040236327).

Paul et al. disclose the claimed invention except for the device, being made of biocompatible metal, synthetic and metal-synthetic materials, and the longitudinal

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element being a monolith with at least one of the first or second elements, and the first and second elements having cross-sections/circumferences larger than the longitudinal member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spacer element of a biocompatible metal, or a synthetic or metal-synthetic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Paul et al. with the longitudinal element being a monolith with at least one of the first or second elements, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). It would have been an obvious matter of design choice to construct the device of Paul et al. with the first and second elements having cross-sections/circumferences larger than the longitudinal member, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claim 40 is rejected under 35 U.S.C. 103(a) as being obvious over McAfee (US 20040143264) in view of Jacobsen et al. (US 6530934).

McAfee discloses the claimed invention except for spacer having male and female interlocking parts.

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Jacobsen et al. discloses spacers that having male and female interlocking parts to allow nesting when in an insertion instrument (see FIG. 6, col. 9, lines 43-46).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spacer with male and female interlocking parts in view of Jacobsen to allow nesting when in an insertion instrument.

Response to Arguments

Applicant's arguments filed 06/28/2007 have been fully considered moot. As discussed above, the examiner maintains that the Paul et al. reference discloses the claimed invention; however, it is noted that Applicant is using a different interpretation of the reference, i.e. the examiner is citing different embodiments than what were previously cited

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: previously cited references Ritland US 2003/0191470, Ferree US 2003/0220643, and Biedermann US 2004/0049190

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER